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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,255	07/31/2003	Michael J. Heller	612,404-424	3292

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,255	HELLER, MICHAEL J.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The specification does not reflect the current status of applications sited therein.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the

invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. For convenience, claim 1 is reproduced below.

1. **A method for forming a multiple identity substrate material comprising the steps of:**

providing a first affinity sequence at multiple locations on a support;

providing a functionalized second affinity sequence, which reacts with the first affinity sequence, and has an unhybridized overhang sequence; and

selectively cross-linking first affinity sequences and second affinity sequences.

5. Page 7, bridging to page 8 of the disclosure provides a summary of the invention, and a description of its application.

This invention relates to methodologies and manufacturing techniques which utilize programmable functionalized self-assembling nucleic acids, nucleic acid modified structures, and other s elective affinity or binding moieties a s building blocks for: (1) creating molecular electronic and photonic mechanisms', (2) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components onto silicon or other materials; (3) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components within perimeters of microelectronic or optoelectronic components and devices', (4) for creating, arraying, and manufacturing photonic and electronic structures, devices, and systems; (5) for the development of a high bit density (large byte) three and four dimensional optical data storage materials and devices; and (6) for development of low density optical memory for applications in authentication, anti-counterfeiting, and encryption of information in documents or goods. This invention also relates to associated microelectronic and optoelectronic devices, systems, and manufacturing platforms which provide electric field transport and selective addressing of self- assembling, nanostructures, sub-micron and micron size components to selected locations on the device itself or onto other substrate materials.

6. A review of the disclosure fails to find an adequate written description of a method whereby useful sequences would be identified, and used in the method such that data storage and retrieval can be achieved, be the resultant product used in an electronic or photonic mechanism.

Further, the specification has not been found to set forth such full, clear, and concise language that which would permit one of skill in the art to recognize the resultant multiple identity substrate that is useful in data storage and retrieval from that which is not useful.

Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

7. The specification has shown that four oligonucleotide sequences have been used in a method whereby a "nanostructure" was created. The specification, however, does not go one to show that any one, much less all, of these nanostructures were used or useful in "(1) creating molecular electronic and photonic mechanisms', (2) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components onto silicon or other materials; (3) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components within perimeters of microelectronic or optoelectronic components and devices', (4) for creating, arraying, and manufacturing photonic and electronic structures, devices, and systems; (5) for the development of a high bit density (large byte) three and four dimensional optical data storage materials and devices; [or] (6) for development of low density optical memory for applications in authentication, anti-counterfeiting, and encryption of information in documents or goods."

8. For the above reason, and in the absence of convincing evidence to the contrary, claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

9. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

A review of he disclosure finds an example where a nanostructure was made. However, the specification is silent as to how one is to use the nanostructure in any of the recited and intended utilities. It is not enough that the specification teaches how to make a novel product. The specification must enable the use of that which is produced. In the instant case4, the specification is essentially silent as to how one is to use the resultant product in any disclosed method that withstands a test of utility. Therefore, and in the absence of convincing evidence to the contrary, claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

10. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible and substantial asserted utility or a well established utility.

11. The specification lists 6 intended utilities for the resultant product: (1) creating molecular electronic and photonic mechanisms', (2) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components onto silicon or other materials; (3) for the organization, assembly, and interconnection of nanostructures, submicron and micron sized components within perimeters of microelectronic or optoelectronic components and devices', (4) for creating, arraying, and manufacturing photonic and electronic structures, devices, and systems; (5) for the development of a high bit density (large byte) three and four dimensional optical data storage materials and devices; and (6) for development of low density optical memory for applications in authentication, anti-counterfeiting, and encryption of information in documents or goods." Of the six recited utilities, 1-4 are not viewed as being substantial. For example, manufacturing "molecular electronic and photonic mechanisms" for

the sake of making them, when they have no specific and substantial utility is not deemed to meet the utility requirements of 35 USC 101. Similarly, the organization of nanostructures or for their interconnection does not in and of its self rise to the level of a substantial utility.

12. Utilities identified as elements (5) and (6) are deemed to be substantial, however, they are not found to be credible. As set forth above, the specification has not been found to provide an adequate written description of resultant "multiple identity substrate material" that has been disclosed as useful in a reproducible method, where such method is any of the disclosed utilities.

13. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible or substantial asserted utility or a well established utility.

14. Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

16. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

17. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-126 of U.S. Patent No. 6,652,808 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the '808 patent are drawn to a like method of producing microscale or nanoscale structure that comprise a DNA sequences, which, a seen in claim 7 of the instant application, can comprise 3 sequences, which corresponds to claim 1 of said patent.

19. In view of such detailed teachings, one of skill in the art would have been motivated to devise a method of making such NDA-bearing structures, and to have done so with a most reasonable expectation of success.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
23 January 2006